K013038

AUG 14 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS for the SAFE MAXI OXYGENATOR as required by section 807.92(c).

Submitter's Information

Name:	POLYSTAN A/S
Address:	Walgerholm 8, 3500 Værløse, Denmark
Phone:	+ 45 44 65 15 66
Fax	+ 45 44 68 15 66
Contact person:	Dana Olsen, Regulatory Affairs
Date of preparation:	May 27, 2002

Device name:

Trade Name:	SAFE MAXI hollow fiber oxygenator
Common/Usual name:	membrane oxygenator
Classification name:	Cardiopulmonary bypass oxygenator (21 CFR – 870.4350)

Predicate Device Name(s):

Quadrox HMO 1010 HF Membrane Oxygenator – Jostra AG – 510(k) no. K992559.

Device Description

SAFE MAXI is a hollow fiber oxygenator with an integral venous heat exchanger. The SAFE MAXI oxygenator is a single-use, disposable, sterile and non-pyrogenic device. The overall blood flow path is from bottom to top in the heat exchanger module and top to bottom in the gas exchange section. The inverted "U" shaped blood flow path optimizes the device's bubble trapping capabilities. Gas exchange occurs by diffusion across the porous hollow fiber membrane.

Intended Use

The SAFE MAXI hollow fiber oxygenator is intended for use in an extracorporeal circuit to oxygenate and remove carbon dioxide from blood and to regulate the blood temperature during cardiopulmonary bypass procedures up to 6 hours in duration.

Technological Characteristics Summary

When compared to the predicate device the SAFE MAXI oxygenator has some different technological characteristics, e.g. design.

In order to demonstrate that the SAFE MAXI oxygenator is substantially equivalent to the currently marketed Quadrox HMO 1010 HF Membrane Oxygenator (Jostra AG) biocompatibility and in-vitro testing was performed.

- Biocompatibility Testing
  - *In vitro* Cytotoxicity Test (Elution Test)
  - Test for Delayed Contact Hypersensitivity using the Guinea Pig Maximization Test (Sensitization)
  - Intracutaneous Test in the Rabbit
  - Systemic Injection Test in the Mouse
  - Haemolysis Test (Haemocompatibility)

Based on the biocompatibility testing performed, the SAFE MAXI oxygenator was determined to be biocompatible and safe for its intended use.

- *In vitro* Bench Testing

In vitro bench testing was performed according to the FDA's *"Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff"* of November 13, 2000. Reference to the ISO 7199:1996 standard was made where appropriate.

Physical Characteristics
- Blood Pathway Integrity
- Heat Exchanger Fluid Pathway Integrity
- Gas Pathway Integrity
- Blood Volume Capacity
- Connectors

Performance Characteristics
- Oxygen Gas Transfer
- Carbon Dioxide Gas Transfer
- Blood Cell Damage
- Blood Side Pressure Drop
- Heat Exchanger Performance
- Water Side Pressure Drop

- *In vivo* Testing
  - Animal testing was performed

Conclusion:

The biocompatibility, performance, and function data demonstrated that the SAFE MAXI oxygenator is substantially equivalent to the predicate device Jostra Quadrox HMO 1010 HF Membrane Oxygenator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2002

POLYSTAN A/S
c/o Ms. Dana Olsen
8, Walgerholm
DK-3500 Værløse - Denmark

Re: K013038
SAFE MAXI Hollow Fiber Oxygenator
Regulation Number: 870.4350, 870.4240
Regulation Name: CPB Oxygenator, CPB Heat Exchanger
Regulatory Class: Class II (two)
Product Code: DTZ and DTR
Dated: May 29, 2002
Received: May 31, 2002

Dear Ms. Olsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

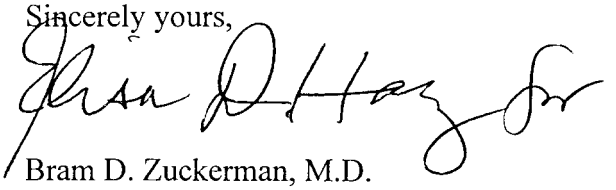
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indication for Use

Statement of Indication for Use

The SAFE MAXI – hollow fiber oxygenator is intended for use in an extracorporeal circuit to oxygenate and remove carbon dioxide from blood and to regulate the blood temperature during cardiopulmonary bypass procedures up to 6 hours in duration.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K013038

Prescription Use ✓ OR Over-The-Counter Use __